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BIRCH STEWART KOLASCH & BIRCH		
PO BOX 747		
FALLS CHURCH, VA 22040-0747		

EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/520,350

Applicant(s)

KOMORI ET AL.

Examiner

Li Zheng

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/29/2007; 2/17/2006; 1/4/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-13 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-4, and SEQ ID NO: 69 in the reply filed on 11/7/2007 is acknowledged. Applicants traverse all the restriction requirements.

Applicants contend that searching all the groups including all the nucleotides in a single application does not present undue burden (response, page 3, 2nd paragraph).

The Office maintains that the search and examining of all groups together is undue. While the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office. Further, the instant application is a national stage of a PCT, the restriction requirement is based on the lack of the unity. The Office does not have to establish a search burden for the restriction requirement.

Applicants further contend that the Examiner cannot properly restrict an application by dividing up the subject matter of a single generic claim by making a restriction within the claim (response, page 3, last paragraph).

The Office contends that the sequence election is NOT considered as an election of species. Applicants are, again, reminded that nucleotide sequences encoding

different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicants further request to rejoin SEQ ID NO: 27 with SEQ ID NO: 69 in that SEQ ID NO: 69 is a subsequence of SEQ ID NO: 27 (response, page 4, 2nd paragraph). Applicants' request is granted. In addition, during the examination, a sequence search reveals that SEQ ID NO: 69 is a also subsequence of SEQ ID NO: 70-74, 80-83 and 85 and that SEQ ID NO: 69 has only 1 base mismatch to SEQ ID NO: 84. Therefore, there is no search burden to search for all the sequences together. The restriction among SEQ ID NO: 27, 69-74 and 80-85 are withdrawn.

Applicants are advised that since the restrictions between SEQ ID NO: 27, 69-74 and 80-85 are withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply.

MPEP804.01.

Claims 5-13 are withdrawn for being drawn to non-elected inventions.

Claims 1-4 including SEQ ID NO: 27, 69-74 and 80-85 are examined on the merits.

The requirement is deemed proper and is therefore made **FINAL**.

Specification

3. The use of the trademarks "ExTaq™" and "MetaPhor™" has been noted in this application (See, for example, pages 67, 79, 95, 96, 97 and 100). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention:

4. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, the recitation "moderate or high" renders the claims indefinite. The recitation is a relative term with no definite meaning. It is unclear what is considered to be a "moderate or high" stringent condition. The metes and bounds are not clear.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method using a nucleotide sequence which encodes an amino acid sequence having at least 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 75; or a nucleotide sequence having at least 70% sequence identity to the bases of 215-2587 of SEQ ID NO: 69; or a nucleic acid

hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition; or any variants of the bases of 215-2587 of SEQ ID NO: 69 by addition, deletion or substitution.

The specification teaches map-based cloning of a dominant fertility restoring gene, Rf-1, from rice (pages 103-150) and isolation and characterization of several Rf-1 cDNA clones (SEQ ID NO: 27, 69-74 and 80-85) encoding SEQ ID NO: 75 (page 145, lines 6-14; the paragraph bridging pages 151-152).

The Applicants do not identify any essential regions of the protein of SEQ ID NO:75, nor do Applicants describe any nucleotide sequence which encodes an amino acid sequence having at least 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 75; or any nucleotide sequence having at least 70% sequence identity to the bases of 215-2587 of SEQ ID NO: 69; or any nucleic acid hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition; or any variants of the bases of 215-2587 of SEQ ID NO: 69 by addition, deletion or substitution, except for the bases 215-2587 of SEQ ID NO: 69 encoding SEQ ID NO: 75.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice

to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of nucleotide sequences which encode an amino acid sequence having at least 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 75; or nucleotide sequences having at least 70% sequence identity to the bases of 215-2587 of SEQ ID NO: 69; or nucleic acids hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition; or any variants of the bases of 215-2587 of SEQ ID NO: 69 by addition, deletion or substitution. Applicants only describe a single ORF encoding SEQ ID NO: 75 in cDNA sequences of SEQ ID NO: 27, 69-74 and 80-85. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein of SEQ ID NO: 75, it remains unclear what features identify a protein of SEQ ID NO: 75. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Scope of Enablement

6. Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for restoring rice fertility comprising introducing a nucleic acid encoding SEQ ID NO: 75 into rice, does not reasonably provide enablement for any nucleotide sequence which encodes an amino acid sequence having at least 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 75, or any nucleotide sequence having at least 70% sequence identity to the bases of 215-2587 of SEQ ID NO: 69, or any nucleic acid hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition, or any variants of the bases of 215-2587 of SEQ ID NO: 69 by addition, deletion or substitution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the

invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method using a nucleotide sequence which encodes an amino acid sequence having at least 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 75; or a nucleotide sequence having at least 70% sequence identity to the bases of 215-2587 of SEQ ID NO: 69; or a nucleic acid hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition; or any variants of the bases of 215-2587 of SEQ ID NO: 69 by addition, deletion or substitution.

The specification teaches map-based cloning of a dominant fertility restoring gene, Rf-1, from rice (pages 103-150) as well as isolation and characterization of several Rf-1 cDNA clones (SEQ ID NO: 27, 69-74 and 80-85) encoding SEQ ID NO: 75 (page 145, lines 6-14; the paragraph bridging pages 151-152).

However, the specification fails to provide guidance in terms of how to make modifications to the SEQ ID NO: 75 to generate the claimed genus of variants that retain fertility restoring activity. It is unclear what the conserved structure is for variants of SEQ ID NO: 75. Even if the conserved structure were known, the state of art teaches that the result of making modification from a known protein is unpredictable.

Falcon-Perez JM et al. (1999, *J Biol Chem.* 274:23584-90) teach that when twenty-two single amino acid substitutions or deletions were introduced into the nucleotide binding domains, the proposed regulatory domain, and the fourth cytoplasmic loop of the yeast cadmium factor (Ycf1p) vacuolar protein by site-directed

mutagenesis, two conserved amino acid residues, Glu (709) and Asp (821), were found to be unnecessary for Ycf1p biogenesis and function.

The state of art also teaches that making "conservative" substitutions (e.g., substituting one polar amino acid for another, or one acidic one for another) does not produce predictable results. Lazar et al. (1988, Mol. Cell. Biol. 8:1247-1252) teach that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). All these mutated proteins would have at least 95% identity to the original protein.

Guo et al. (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2).

Therefore, the instant specification fails to provide guidance for which amino acids of SEQ ID NO: 75 can be altered, the type of alteration, and which amino acids must not be changed, to maintain the activity of the encoded protein. The specification

also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

Further regarding the use of a nucleic acid hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition, given the undefined term of "moderate or high stringent condition", any nucleic acid would be able to hybridize to other unrelated nucleic acid more or less. Therefore, as discussed above, the methods using such claimed nucleic acids are clearly not enabled.

Even if the hybridization condition were well defined and highly stringent, the claims would still not be enabled. The state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotides mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment of

Frougoux-Nicol et al exhibits less than 50% sequence identity with the probe to which the fragment hybridized.

Further, the specification did not provide guidance on how to use reverse complement DNA strand of SEQ ID No. 27, 69-74 and 80-85. The nucleic acids hybridizable to SEQ ID No. 27, 69-74 and 80-85 are expected to be reverse complement to them and are unlikely to have fertility restoring activity.

Still further, claim 4 requires a limitation that "a base corresponding to the base 1769 of SEQ ID NO: 69 is A". Such limitation implies that the residue can only be Asn, Lys, Ile, Ser, Arg or Met. However, the specification does not provide guidance on conserved domains of SEQ ID NO: 75. Therefore, it is not clear at all that which residue in the homologs of SEQ ID NO: 75 is corresponding to the one of Asn, Lys, Ile, Ser, Arg or Met and that which base of claimed nucleic acid is corresponding to the base 1769 of SEQ ID NO: 69 is A. Even if the residue is highly conserved, the claim is still not enabled because a residue that can be Asn, Lys, Ile, Ser, Arg or Met cannot be considered to be a conserved residue.

Without further guidance, undue experimentation would be required for a person skilled in the art to develop and evaluate nucleotide sequences which encode an amino acid sequence having at least 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 75; or nucleotide sequences having at least 70% sequence identity to the bases of 215-2587 of SEQ ID NO: 69; or nucleic acids hybridizing to the bases of 215-2587 of SEQ ID NO: 69 at moderate or high stringent condition; or any variants of the bases of 215-2587 of SEQ ID NO: 69 by addition, deletion or substitution. See

Genentech Inc. v. Novo Nordisk, A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Therefore, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanson et al. (U.S. Patent No. 7,164,058).

The claims are drawn to a method for restoring rice fertility comprising introducing a nucleic acid into rice, wherein the nucleic acid encodes an amino acid sequence that is at least 70% identical to the amino acid sequence of SEQ ID NO: 75; or wherein the nucleic acid is at least 70% identical to the bases of 215-2587 of SEQ ID

NO: 69.

Hanson et al. teach an isolated nucleotide sequence of SEQ ID NO: 22 from rice, which encodes a protein of SEQ ID NO: 23 and restores fertility to cytoplasmic male sterile plants (column 5, lines 60-65). The sequence search reveals that SEQ ID NO: 22 is 87.6% identical to SEQ ID NO: 69 of instant application and that SEQ ID NO: 23 is 84.4% identical to SEQ ID NO: 75 of instant application (see sequence alignments 1 & 2 attached). Hanson et al. also teach introducing the SEQ ID NO: 22 into a sterile plant by crossing (column 6, lines 32-39). Since SEQ ID NO: 22 is from rice, "restoring the rice fertility" is thus inherently exhibited by the teaching of Hanson et al. Therefore the reference teaches all the limitations set forth by the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 10/560,736 ('736 hereafter). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims 1-4 are drawn to a method using a nucleotide sequence which encodes a protein of SEQ ID NO: 75 and the variants thereof.

Claim 6 of '736 is drawn to a hybrid plant comprising a fertility restore gene encoding SEQ ID NO: 49, which is 100% identical to SEQ ID NO: 75 in instant application, or the variants thereof in two or more not completely linked loci. To make such hybrid plant, it would have been obvious to introduce the restore gene encoding SEQ ID NO: 49 into a rice plant at least once. One would have been motivated to do so because it is the most conventional way to introduce a new trait into a plant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

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No claim is allowed. However, the method for restoring rice fertility comprising introducing nucleotide sequences encoding SEQ ID NO: 75 is free of prior art due to the failure of the prior to teach or fairly suggest the nucleotide sequences encoding SEQ ID NO: 75.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER